K120406

510(k) Summary:

OCT 2 6 2012

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

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(978) 421-9171

Date Summary Prepared:

February 8, 2012

Device:

ZOLL Fully Automatic AED Plus

Classification:

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

The predicate ZOLL AED Plus with 2010 AHA Guideline software update was cleared by the agency under 510(k) application K110154. The device is a lightweight, portable, battery-powered semi-automatic external defibrillator that uses voice prompts and visual icons to guide a user through a cardiac arrest rescue. The device utilized the ZOLL Rectilinear Bi-Phasic defibrillation waveform. The device is designed to be used by trained responders for the treatment of cardiac arrest.

When connected with ZOLL AED Plus defibrillation electrodes to a patient, the predicate device will analyze the electrocardiographic (ECG) rhythm of the patient and detect whether the rhythm is shockable or non-shockable. If the device detects a non-shockable rhythm, the device will prompt the user to begin CPR. The electrodes used with the device incorporates an accelerometer that measures the depth of CPR compressions. This information is used by the device to provide feedback to the user and encourage the user to administer CPR in compliance with the 2010 American Heart Association (AHA) Guidelines. If the device detects a shockable rhythm, the semi-automatic configuration of the device charges the capacitor, enables the treatment button and prompt the user to deliver the defibrillation energy to the patient. The user would then press the treatment (shock) button to deliver the defibrillation shock to the

patient. The new fully automatic configuration would deliver the shock to the patient without the need for the user (rescuer) to press the shock button.

The following is a comparison summary of the new Fully Automatic AED Plus when compared to the predicate device:

- When a shockable rhythm has been detected defibrillation energy is delivered by the device without the need for the user (rescuer) to depress the treatment (shock) button following a sequence of appropriate prompts and a warning tone.

- All other functions of the device and its Indications for Use have remained unchanged.

- The proposed change is implemented in the device through software.

Intended Use:

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation

When a victim is less than 8 years of age, or weighs less than 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Substantial Equivalence:

The features and functions of the new ZOLL Fully Automatic AED Plus are substantially equivalent to the predicate ZOLL AED Plus (K110154, cleared for use on 2/17/2011).

Comparison of Technological Characteristics

The technological characteristics of the new ZOLL Fully Automatic AED Plus are substantially equivalent to the predicate ZOLL AED Plus (K110154, cleared for use on 2/17/2011).

Performance Testing:

Extensive performance testing ensures that the ZOLL Fully Automatic AED Plus performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL Fully Automatic AED Plus demonstrates that its features and functions are substantially equivalent to those of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

Zoll Medical Corporation
c/o Mr. Tanmay Shukla
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824

Re: K120406
Trade/Device Name: Zoll AED Plus Fully Automatic
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: October 17, 2012
Received: October 18, 2012

Dear Mr. Shukla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **ZOLL Fully Automatic AED Plus**

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation

When a victim is less than 8 years of age, or weighs less than 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120406